

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claims 1-21 (Canceled).

Claim 22 (currently amended): A process for preparing a carrier for use in the preparation of powdery mixtures for the administration by inhalation of micronized drugs, said carrier comprising a plurality of particles, wherein said plurality of particles has a median diameter greater than 90 micron and a surface rugosity expressed as the fractal dimension of less than or equal to 1.1, said process comprising:

subjecting the plurality of particles having a median diameter of greater than 90 micron to repeated stages of wetting with a solvent and drying in a high-speed granulator, and wherein said solvent is a short-chain aliphatic alcohol or a water and alcohol mixture.

Claim 23 (previously presented): The process according to Claim 22, wherein said plurality of particles has a median diameter of from 90 to 150 micron.

Claim 24 (previously presented): The process according to Claim 22, wherein said plurality of particles has a surface rugosity of from 1.0 to 1.1.

Claim 25 (previously presented): The process according to Claim 22, wherein the carrier particles are made of a physiologically acceptable inert material selected from the group consisting of glucose, mannose, galactose, sorbitol, mannitol, lactose, saccharose, trahalose, raffinose, cyclodextrins and mixtures thereof.

Claim 26 (currently amended): The process according to Claim 22, wherein a carrier ~~substantially~~ free from fine particles is obtained.

Claim 27 (currently amended): The process according to Claim 22, ~~comprising~~
~~carrying out the repeated stages of wetting and drying in a high-speed granulator,~~
~~wherein~~ said high-speed granulator ~~consisting of~~ comprises a cylindrical mixing chamber
comprising a rotating paddle (~~impeller~~) and a sprayer, and

wherein said high-speed granulator is capable of operating at controlled temperature
and pressure.

Claim 28 (previously presented): The process according to Claim 27, wherein the
high-speed granulator is a Roto J. Zanchetta or a Diosna apparatus.

Claim 29 (previously presented): The process according to Claim 27, wherein the
total mixing time during the repeated stages of wetting and drying is from 120 to 300
minutes.

Claim 30 (canceled).

Claim 31 (previously presented): The process according to Claim 22, wherein the
solvent is a water-alcohol mixture and the ratio between the water and alcohol is from 9:3 to
3:4 v/v.

Claim 32 (previously presented): The process according to Claim 23, wherein said plurality of particles has a surface rugosity of from 1.0 to 1.1.

Claim 33 (previously presented): The process according to Claim 28, wherein the total mixing time during the repeated stages of wetting and drying is from 120 to 300 minutes.

BASIS FOR THE AMENDMENT

Applicants have amended Claim 22 to recite “in a high-speed granulator, and wherein said solvent is a short-chain aliphatic alcohol or a water and alcohol mixture.” Support for amended Claim 22 can be found in Claims 22, 27, and 30, as previously presented.

No new matter has been added. Claims 22-29 and 31-33 remain active in the present application.

REMARKS/ARGUMENTS

Present Claims 22-29 and 31-33 relate to processes for preparing a carrier for use in the preparation of powdery mixtures for the administration by inhalation of micronized drugs, said carrier comprising a plurality of particles, wherein said plurality of particles has a median diameter greater than 90 micron and a surface rugosity expressed as the fractal dimension of less than or equal to 1.1, said process comprising:

subjecting the plurality of particles having a median diameter of greater than 90 micron to repeated stages of wetting with a solvent and drying in a high-speed granulator, and wherein said solvent is a short-chain aliphatic alcohol or a water and alcohol mixture.

The inventors have discovered that the presently claimed processes are particularly effective for obtaining carrier for use in the preparation of powdery mixtures for the administration by inhalation of micronized drugs. The cited references contain no disclosure or suggestion of the presently claimed processes or the advantages afforded thereby. Accordingly, these references cannot affect the patentability of the present claims.

The rejection of Claims 22-26 and 32 under 35 U.S.C. § 102(b) in view of U.S. Patent No. 5,376,386 (Ganderton et al.) and the rejection of Claims 27-31 and 33 under 35 U.S.C. §